

SHORT TITLE: Harmony Outcomes Trial

RESEARCH PROTOCOL TITLE: A long term, randomized, double-blind, placebo-controlled study to determine the effect of albiglutide, when added to standard bold glucose lowering therapies, on major cardiovascular events in patients with type two diabetes mellitus.

PRINCIPAL INVESTIGATOR: David Lewis, MD

RESEARCH SPONSOR: GlaxoSmithKline

Clinical Trials.Gov Listing at:

<https://clinicaltrials.gov/ct2/show/NCT02465515?term=albiglutide&rank=17>

STUDY PURPOSE

People with type 2 diabetes have a higher risk of getting cardiovascular disease (disease of the heart and/or blood vessels) than people without diabetes. Cardiovascular disease may cause serious complications such as heart attack or stroke.

Albiglutide is a medicine (given as a weekly injection) used to lower blood sugar levels in people with diabetes. The purpose of this study is to find out whether people taking albiglutide for diabetes have a higher or lower risk of developing cardiovascular complications (heart attack, stroke, or death from cardiovascular disease), than people who do not take albiglutide.

STUDY PROCEDURES

The study will last between 3 and 5 years with study visits every 4 months. During the study visits vital signs (weight, blood pressure and pulse) will be taken, questionnaires completed, and study medication will be collected and re-dispensed. Some visits will include a physical exam by a study doctor.

ELIGIBILITY CRITERIA FOR SUBJECTS

40 years or older

A diagnosis of Diabetes Mellitus Type 2

Established cardiovascular disease

SUBJECT PAYMENT

Participants will be compensated \$50 (fifty) for each completed study visit.

RESEARCH LOCATION AND CONTACT PERSON

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